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**ASSISTANT COMMISSIONER FOR PATENTS  
BOX PATENT APPLICATION  
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Sir:

Transmitted herewith for filing under 37 CFR 1.53(b) is the

- ☐ patent application of  
☒ continuation patent application of  
☐ divisional patent application of  
☐ continuation-in-part patent application of

Attorney Docket No. 14635-007890US

Client Ref No. 001-D2-C2

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By:

STUART MCLEISH

Inventor(s)/Applicant Identifier: HENNING R. ANDERSON, JOHN M. HASENKAM and LARS L. KNUDSEN

For: A VALVE PROSTHESIS FOR IMPLANTATION IN THE BODY AND A CATHETER FOR IMPLANTING SUCH  
VALVE PROSTHESIS

☒ This application claims priority from each of the following Application Nos./filing dates:

09/026,574, filed 2/20/98; 08/955, 228, filed 10/1/97; 08/801,035, filed 2/19/97; 08/569,314, filed 12/08/95; 08/352,127,  
filed 12/1/94; 08/261,235, filed 6/14/94

the disclosure(s) of which is (are) incorporated by reference.

Enclosed are:

- ☒ 14 page(s) of specification  
☒ 2 page(s) of claims  
☒ 1 page of Abstract  
☒ 4 sheet(s) of formal drawing(s).

The application is assigned of record to HEARTPORT, INC.

A copy of the signed Declaration & Power of Attorney from the prior application.

A verified statement to establish small entity status under 37 CFR 1.9 and 37 CFR 1.27 was filed in the prior application and small  
entity status is still proper and desired.

Incorporation By Reference: the entire disclosure of the prior application, from which a copy of the Oath or Declaration is supplied  
is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.

A preliminary amendment.

A copy of the notification of change of correspondence address filed in prior application.

	(Col. 1)	(Col. 2)
FOR:	NO. FILED	NO. EXTRA
BASIC FEE		
TOTAL CLAIMS	12 - 20	= *0
INDEP. CLAIMS	2 - 3	= *0
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Respectfully submitted,  
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Date of Deposit February 28, 2000

PATENT

Attorney Docket No.: 14635-007890US

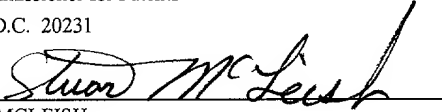
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By:

  
STUART MCLEISH

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

HENNING R. ANDERSON, et al.

Application No.: Unassigned

Filed: Herewith

For: A VALVE PROSTHESIS FOR  
IMPLANTATION IN THE BODY  
AND A CATHETER FOR  
IMPLANTING SUCH VALVE  
PROSTHESIS

Art Unit: Unassigned

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents

Washington, D.C. 20231

Sir:

Prior to examination of the above-referenced application, please enter the following amendments and remarks.

IN THE SPECIFICATION:

At page 1, lines 5 through 9, please delete the entire first paragraph and insert the following instead:

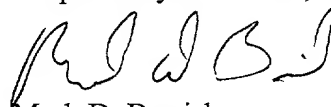
--This application is a continuation of co-pending application Serial No. 09/026,574, filed February 20, 1998, which is a continuation of application Serial No. 08/955,228, filed October 1, 1997, now abandoned, which is a division of 08/801,036, filed February 19, 1997, now issued as U.S. patent no. 5,840,081, which is a continuation of 08/569,314, filed December 8, 1995, now abandoned, which is a continuation of application

08/352,127, filed December 1, 1994, now abandoned, which is a division of application  
08/261,235, filed June 14, 1994, now issued as U.S. patent no. 5,411,552.--

CONCLUSION

If the Examiner believes a telephone conference would expedite prosecution of  
this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,



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MDb:lmc  
PA 3053630 v1

**A VALVE PROSTHESIS FOR IMPLANTATION IN THE BODY AND A  
CATHETER FOR IMPLANTING SUCH VALVE PROSTHESIS**

**CROSS REFERENCE TO RELATED APPLICATION**

5           This application is a continuation of co-pending application Serial No.  
08/955,228 filed October 1, 1997, which is a division of application Serial No.  
08/801,036 filed continuation of application Serial No. 352,127, filed December 1,  
1994, now abandoned, which is a divisional of Serial No. 261,235, filed June 14,  
1994, now U.S. Patent. No. 5,411,552.

10

**BACKGROUND OF THE INVENTION**

The present invention relates to a valve prosthesis, preferably a cardiac valve  
prosthesis, for implantation in the body and comprising a collapsible elastic valve  
which is mounted on an elastic stent wherein the commissural points of the elastic  
15 collapsible valve are mounted on the cylinder surface of the elastic stent.

Valve prostheses of this type are usually implanted in one of the channels of the body  
to replace a natural valve. In the present description the invention will be explained in  
connection with a cardiac valve prosthesis for implantation in aorta. However, it will  
20 be possible to use a valve prosthesis according to the invention in connection with  
implantation in other channels in the body by using the same technique as the one  
used for implantation of cardiac valve prosthesis. Such an implantation may, e.g.,  
comprise the implantation of:

1. a valve (for instance a cardiac valve) in the veins,
- 25 2. a valve in the esophagus and at the stomach,
3. a valve in the ureter and/or the vesica,
4. a valve in the biliary passages,
5. a valve in the lymphatic system, and
6. a valve in the intestines.

30

An existing natural valve in the body is traditionally replaced with a valve prosthesis  
by a surgical implantation. However, a surgical implantation is often an exacting  
operation. Thus, today the implantation of cardiac valves are solely made by surgical

technique where the thoracic cavity is opened. The operation calls for the use of a heart and lung machine for external circulation of the blood as the heart is stopped and opened during the surgical intervention and the artificial cardiac valves are subsequently sewed in.

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Due to its exacting character, it is impossible to offer such operation to certain people. For instance, this is due to the fact that the person is physically weak because of age or illness. Moreover, the number of heart and lung machines available at a hospital will be a substantially limiting factor.

10

Cardiac valve prostheses that need no surgical intervention are known as there are used for implantation by means of a technique of catheterization. Examples of such valve prostheses are described in U.S. Patent Nos. 3,671,979 and 4,056,854.

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However, both of these valve prostheses are connected to means which lead to the surface of the patient either for a subsequent activation of the valve or for a subsequent reposition or removal of the valve prosthesis. With these valve prostheses it is impossible to make an implantation which makes it possible for the patient to resume a substantially normal life in the same way as it is possible in connection with a surgical implantation of a cardiac valve.

20

From U.S. Patent No. 3,755,823 an elastic stent for a cardiac valve prosthesis is known. However, this valve prostheses is not designed for implantation in the body by catheterization. Even though this patent contains no detailed explanation, the description indicates that this valve prosthesis is designed for implantation and sewing on by a surgical intervention.

25

Moreover, from U.S. Patent Nos. 4,856,516 and 4,733,665 different shapes of expandable stents are known. These stents are made to be expanded by impression of a radially outward force coming from a balloon catheter or the like. These stents are made to reinforce the wall when there is a risk that the channel is closed and/or compressed.

30

The nearest prior art may be that the described in GB-A-2.056.023. This document discloses an elastic stent as described by way of introduction. Thus, the stent described comprises an elastic collapsible valve mounted on the cylinder surface of a cylindrical stent. However, the valve prosthesis including the stent is designated for mounting through a surgical intervention. Even though the stent is slightly collapsible, it will not be suited for implantation by a catheterization procedure.

### SUMMARY OF THE INVENTION

It is the object of the present invention to provide a valve prosthesis of the type mentioned in the introductory part, which permits implantation without surgical intervention in the body and by using a catheter technique known per se and which makes it possible for the patient to resume a substantially normal life.

This is achieved according to the invention with a valve prosthesis of the type mentioned in the introductory part, which is characterized in that the stent is made from a radially collapsible and re-expandable cylindrical support means for folding and expanding together with the collapsible valve for implantation in the body by means of a technique of catheterization.

The collapsible elastic valve is mounted on the stent for instance by gluing, welding or by means of a number of suitable sutures.

If the support means are made from a thread structure, this can for instance be grate shaped, loop shaped or helical. This makes it possible to compress the stent and the collapsible valve mounted thereon for placing on the insertion catheter. The use of a non-self-expandable stent may, e.g., be effected by a compression of the stent around the expansion arrangement of the catheter which preferably consists of a balloon.

When using a self-expandable stent, a catheter with an expansion arrangement is not used. In this case the stent is compressed and is inserted into an insertion or protection cap from which the stent is eliminated after implantation in order to obtain an expansion due to the stresses in the compressed support means, which for instance may be made from plastics or metal. After the compression the entire outer dimension is relatively small, which makes it possible to introduce the valve

prostheses through a channel in the body.

When the valve prosthesis is introduced and placed correctly, the stent is expanded by self-expansion or by means of the expansion arrangement until the stent is given an  
5 outer dimension which is slightly larger than the channel in which it is placed. As the stent is elastic, a contraction of the stent is prevented once it is expanded. The stiffness in the material of the support means contributes to maintain the expanded shape of the stent. After the expansion is made, the expansion arrangement of the catheter is contracted and the catheter can be removed from the channel. The inlet  
10 opening can subsequently be closed and the patient will then be able to resume a normal life.

The valve prosthesis according to the invention does not require an actual operation but merely a small intervention to optionally expose the body channel, e.g., a vein,  
15 through which the insertion takes place. Thus, patients for whom an operation would be associated with high risk can be offered implantation of, for instance, cardiac valves. After the implantation has taken place, the after-treatment will advantageously be shorter than normal, which means fewer hospital days for the patient. Moreover, it is assumed that it will be possible to implant the valve  
20 prosthesis under local anaesthetic.

The valve prosthesis can be used to replace a natural valve or to establish a new valve function in one of the channels in the body which do not naturally contain a valve. For instance this goes for veins (arteries and veins) on a place without natural valves.  
25 The function of the valve prosthesis is then to ensure that the blood flows in one direction only. The valve is meant to be used in veins in the legs of persons suffering from varicose veins (varices).

In persons having varicose veins the blood flows in a wrong direction, viz. from the  
30 central veins in the center of the leg towards the superficial veins. Among other things, this is due to the changed pressure in the legs, upright working position and other conditions. A valve prosthesis according to the invention may easily be placed in the veins and prevent the flow of the blood in a wrong direction.

Also, the valve prosthesis can be used in connection with diseases, for instance cancerous tumors, where too much humour is produced. If the humour is able to flow from the cancerous tumor through several channels, it is possible to drain the humour in one desired direction through the channels of the body by an appropriate placing of the valve prosthesis.

When the valve prosthesis is used as a cardiac valve prosthesis in the aorta, it is possible to mount it in three positions, viz., in the descending part of the aorta in a position between the coronary arteries and the left ventricle of the heart, or in the aorta in a position immediately after the mouth of the coronary arteries.

The cardiac valve prosthesis can also be used in other places than in the aorta. Thus, the valve prosthesis can be used in the pulmonary artery and/or the right ventricle of the heart for replacing the pulmonary valves. Likewise, the cardiac valve prosthesis can be used in the passage between the right auricle of the heart and the right ventricle of the heart (tricuspidalostium) and the passage between the left auricle of the heart and the left ventricle of the heart (mistralostium) for replacing the tricuspidal valve and the mitral valve, respectively.

Even though the cardiac valve preferably is meant to be used for patients suffering from aorta insufficiency and who cannot be offered an open heart surgery, the valve prosthesis can also be used for patents in connection with treatment of aorta stenosis. Several of the patients with aorta stenosis are elderly people who cannot be offered a surgical cardiac operation. The patients are offered balloon dilatation of the aorta stenosis which may result in an aorta insufficiency as a side effect of the treatment.

As to these patients it is possible to insert a valve prosthesis in the descending or ascending part of the aorta thoracalis a few days or weeks before the balloon dilatation. As a result thereof, the left ventricle is protected against weight if the subsequent balloon dilatation of the stenosis results in aorta insufficiency. In certain cases the weight (reflux) on the left ventricle is reduced by up to approximately 75%.



Furthermore, the stent may be made with a relatively great height and with a cylinder surface which is closed by a suitable material. Thus, a vascular prosthesis known per se is formed wherein the valve is mounted. This may facilitate the implantation of the valve prosthesis, for instance in the arcus aorta. Moreover, the great surface which abuts the inner wall of the channel contributes to ensure the securing of the valve prosthesis in the channel. This embodiment is also suitable as valve prosthesis which is inserted in veins. As veins have relatively thin and weaker walls than arteries, it is desirable that the valve prosthesis has a greater surface to distribute the outward pressure which is necessary to secure the valve prosthesis.

Moreover, the invention relates to a balloon catheter for implanting a valve prosthesis according to the invention and comprising a channel for injection of a fluid for the inflation of the balloon means of the catheter and an insertion cap wherein the balloon means of the catheter and a collapsible valve prosthesis mounted thereon are located during the injection, characterized in that the balloon means are provided with profiled surface which is made to ensure a steady fastening of the valve prosthesis during the withdrawal of the balloon means from the protection cap and the subsequent inflation for the expansion of the stent.

Different balloon catheters for implanting cores in the body are known. For instance, such balloon catheters are known from U.S. Patent Nos. 4,856,516, 4,733,665 and 4,796,629 and from DE publication No. 2,246,526. However, the known balloon catheters have a smooth or a slightly wavy surface. The use of such balloon catheter is disadvantageous for mounting a valve prosthesis in a channel having a large flow as for instance the aorta. A large humour flow is able to displace the stent on the smooth surface of the balloon and makes an accurate positioning difficult. This drawback has been remedied with the balloon catheter according to the present invention as the profiled surface prevents a displacement of the valve prosthesis in relation to the balloon means during introduction and the subsequent inflation of the balloon means.

In connection with the implantation, any prior art technique may be used to supervise an accurate introduction and positioning of the valve prosthesis. Thus, guide wires for

the catheter. X-ray supervision. injection of X-ray traceable liquids. ultrasonic measuring, etc. may be used.

#### DESCRIPTION OF THE DRAWINGS

5 The invention will now be explained in detail with reference to the accompanying schematical drawing, wherein

Fig. 1 shows a perspective view of a stent without a valve.

Fig. 2 is a perspective view of a valve prosthesis according to the  
10 invention made from the stent shown in Fig. 1 having a biological valve mounted thereon,

Fig. 3 is a partial view through the aorta illustrating a partially inflated balloon catheter.

Fig. 4 is a cross section through the embodiment shown in Fig. 9.

15 Figs. 5-7 are views illustrating the introduction and implantation of a valve prosthesis of the invention in the aorta,

Figs. 8-10 are views illustrating three possible positions of a cardiac valve prosthesis, and

20 Figs. 11-12 are perspective views illustrating two further embodiments of a valve prosthesis having a closed cylindrical wall.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Fig. 1 shows a stent 1 made by support means in the form of two 0.55 mm surgical stainless steel wires 2,3. The wires are folded in 15 loops. Three loops 4 are 14 mm  
25 in height and are intended to secure the commissural points 5 (see Fig. 2) from a biological cardiac valve 6 which is mounted in the stent 1. The remaining loops have a height of 8 mm. These loops form circumferentially expandable sections 25 between the commissural points 5 forming commissural supports. Each of the two folded wires 2,3 is bent to form rings 7,8 which are closed by welding the ends. The  
30 two rings are placed on top of each other as will appear from Fig. 1 and they are mutually secured by means of a number of sutures (not shown). The lower ring is circumferentially expandable at least along sections thereof which correspond to the circumferentially expandable sections 25. By using a substantially cylindrical thread

structure with projecting apices. a reduction in weight is obtained as compared to a stent which is exclusively cylindrical with the same loop heights for all the loops.

The biological valve 6 was removed from a slaughtered pig of 100kg. The valve was  
5 cleaned before mounting in the stent 1. The cleaned valve has an outer diameter of  
25-27 mm and the height of the three commissural points 5 is 8 mm. The valve 6 is  
mounted in the stent by means of a suitable number of sutures to form the cardiac  
valve prosthesis 9 shown in Fig. 2. The valve prosthesis produced is used for  
performing tests in pigs by implantation of cardiac valve prosthesis. However, the  
10 cardiac valve prosthesis for use in human beings has a corresponding form.

Fig. 3 shows a partial view through the aorta 10. A balloon catheter 11 is introduced  
in the aorta according to the direction of an arrow 12. In the Figure shown the balloon  
means 13 of the balloon catheter is led out of the protection cap 11A and is partly  
15 inflated through a fluid channel 15, which is led to the surface of the patient. The  
balloon means 13 constitutes a tri-sectional balloon upon which the cardiac valve  
prosthesis is placed. In the form shown, the cardiac valve prosthesis is expanded  
exactly to be in contact with the aorta 10. The balloon means 13 is provided with  
three projecting beads 14 which are engaged with the one side of the cardiac valve  
20 prosthesis 9. The blood flowing through the aorta according to the direction of an  
arrow 16 will thus cause the cardiac valve prosthesis 9 to abut on the beads 14 and the  
valve cannot be displaced in relation to the balloon means 13. Moreover, the balloon  
catheter used comprises a central channel 17 to receive a guide wire 18 which is used  
in a way known per se for supervising the introduction of the catheter through  
25 fluoroscopy. In the shown embodiment beads 14 are only used at one side of the valve  
prosthesis, but, however, it will often be desirable to use the beads in pairs placed  
along lines parallel to the longitudinal axes 19 through the balloon means 13. In this  
case the spacing of the pair of beads 14 will correspond to the height of the loops of  
the stent. This makes it possible to make an effective fastening of a valve prosthesis  
30 on balloon means. Moreover, the fastening on the balloon means may be provided by  
using balloon means with an indentation in the surface (not shown).

Fig. 4 shows a cross section through the embodiment shown in Fig. 3 illustrating the placing of the beads 14 on the tri-sectional balloon means 13.

5 A balloon catheter of the above-described type which was used in tests of implanting of cardiac valve prosthesis 9 in pigs had the following dimensions. Each of the three balloons was 60 mm in length and 15 mm in diameter. The total diameter for the three inflated balloons was 31 mm and in the balloon catheter used two beads 14 having a height of 3 mm were mounted on each side of the three balloons. The beads had a spacing of 15 mm. The protection cap 11A of the balloon catheter had an outer diameter of 13.6 mm and an inner diameter of 12.5 mm and a length of 75 cm. The balloon catheter was provided with a standard guide wire having a diameter of 0.9 mm and a length 300 cm.

15 Figs. 5-7 show the valve prosthesis 9 at different steps in introducing and implanting in the aorta 10 by means of the catheter 11 having the inflatable balloon means 13. The cardiac valve prosthesis 9 is initially placed above the deflated balloon means 13 and compressed manually around the balloon means (Fig. 5), whereafter the outer diameter for the valve prosthesis is approximately 10 mm. After the introduction and positioning, the balloon means 13 is inflated (Fig. 6), thereby contributing an outer dimension of approximately 30 mm to the cardiac valve prosthesis. To obtain an effective fastening in the aorta, the outer dimension of the cardiac valve prosthesis is greater than the diameter of the aorta. This means that the prosthesis is tight against the inner wall of the aorta with a pressure which is sufficiently large to counteract a detachment due to the flow of the blood. The balloon catheter 11 may subsequently be removed from the aorta 10 (Fig. 7). Due to the stiffness of the metal the valve prosthesis will prevent a contraction. However, smaller contractions may occur (<10% diameter reduction) after the deflation and removal of the balloon catheter 13. When the valve prosthesis is mounted as shown in Fig. 7, the patient will be able to resume a substantially normal life after a few days.

30 Figs. 8-10 show the positioning of the valve prosthesis 9 as cardiac valve prosthesis in the aorta 10 in three different positions, i.e., in a position between the coronary arteries 20 and the left ventricle of the heart 21 (Fig. 8), in a position immediately

after the mouth of the coronary arteries in the ascending part of the aorta (Fig. 9), and in a position in the descending part of the aorta 10. The positioning of the valve prosthesis is chosen in accordance with the diagnosis of the illness of the patient. By placing the cardiac valve prosthesis as shown in Fig. 8, there is a risk of detachment and/or covering the mouth of the coronary arteries, and therefore it is preferred to use a higher stent which, for instance, comprises several ranges placed on top of each other. This allows a fixation of the prosthesis at a place after the mouth of coronary arteries even though the valve itself is in the position between the coronary arteries and the left ventricle. Figs. 8 and 9 show how a contrast medium 23 is injected by means of a so-called pigtail catheter for registration of tightness of the implanted valve prosthesis 9.

A specific embodiment for a valve prosthesis and a balloon catheter for implanting the valve prosthesis has been explained above. However, it is obvious that it is possible to modify the valve prosthesis depending on the desired use, and moreover, it is possible to modify the catheter used in the implantation. Thus, the stent of the valve prosthesis may be made solely of one closed ring folded in a number of loops or with three or more mutually secured loop-shaped rings placed on top of each other. Moreover, it is possible to make the stent having a thread structure which instead of loops is grate shaped, helical or is formed otherwise if only it is ensured that the form of the stent permits the compression and expansion of the stent and fastening of the collapsible valve. Instead of a biological valve it might be possible to use other collapsible valves, such as valves made from synthetic materials, e.g., polyurethane. It is also possible to use valves with more or fewer flaps than three.

It is possible to make the valve prosthesis with a closed cylinder surface as illustrated in Figs. 11 and 12. In both Figures the support means of the valve prosthesis is made of an elongated tubular means 24 having a closed cylinder surface. This valve prosthesis is intended to expand by self-expansion or by means of a catheter according to the invention. This prosthesis is especially suitable for placing in veins and other channels where only a small pressure is exerted against the wall of the channel. In Fig. 11 the valve 6 is mounted at the end of the tubular means 24. In Fig. 12 an embodiment is shown where the valve 6 is mounted in a central position in the tubular

means 24.

An explanation of a method of implanting a valve prosthesis according to the invention is given below:

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- a valve prosthesis 9 made of a stent 1 and a collapsible valve 6, as described above, is placed on a deflated balloon means and is manually compressed thereon,
- the balloon means 13 and the valve prosthesis are drawn into an insertion cover 11A,
- a guide wire 18 is inserted into the left ventricle of the heart through the central

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- opening 17 of the balloon catheter under continuous fluoroscopy,
- the insertion cover 11A conveys the guide wire 18 to a point in the channel in the immediate vicinity of the desired position of the valve prosthesis,

- the balloon means 13 is pushed out of the protection cap 11A and the valve prosthesis is positioned in the desired position if necessary by use of further

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- registration means to ensure an accurate positioning,
- the balloon means 13 is inflated with a certain overstretching of the channel,
- the balloon means 13 is deflated, and
- the balloon means 13, the guide wire 18 and the protection cap 11A are drawn out and the opening in the channel, if any, wherein the valve prosthesis is inserted can be

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- closed.

WHAT IS CLAIMED IS:

1           1. A valve prosthesis (9), preferably a cardiac valve prosthesis. for implantation  
2     in the body and comprising a collapsible elastical valve (6) which is mounted on an  
3     elastical stent (1) wherein the commissural points (5) of the elastical collapsible valve  
4     (6) are mounted on the cylinder surface of the elastical stent (1) characterized in that the  
5     stent is made from a radially collapsible and re-expandable cylindrical support means  
6     (7,8,24) for folding and expanding together with collapsible valve for implantation in  
7     the body by means of a technique of catheterization.

1           2. A valve prosthesis according to claim 1, characterized in that the support  
2     means (7,8) is made of thread structure (2,3).

1           3. A valve prosthesis according to claim 2, characterized in that the thread  
2     structure (2,3) comprises several spaced apices projecting from the one side of the  
3     cylindrical structure and in direction along the longitudinal axis of the cylinder and that  
4     the commissural points (5) of the valve (6) are attached to the projecting apices.

1           4. A valve prosthesis according to claim 3, characterized in that the elastically  
2     collapsible valve (6) is a biological trilobate valve.

1           5. A valve prosthesis according to claim 4, characterized in that stent (1) is  
2     made from a stainless steel wire (2,3) folded in a number of loops (4) and bended  
3     according to a circle and welded to form a closed ring (7,8), that the stent comprises two  
4     or more such closed rings which are mutually connected end to end to form the  
5     cylindrical thread structure (2,3), that three of the loops (4) in the external ring are  
6     folded with a greater height than the remaining loops to form the apices to which the  
7     commissural points of the biological valve are attached.

1           6. A valve prosthesis according to claim 5, characterized in that each of the  
2     rings (7,8) of the stent (1) is made from a wire having a diameter of 0.55 mm and a loop  
3     height of approximately 8 mm and approximately 14 mm for the three greater loops, and

1 that the cylindrical thread structure produced and the collapsible valve mounted thereon  
2 in a folded state have an outer diameter of approximately 10 mm and in expanded state  
3 an outer diameter of approximately 30 mm.

1 7. A valve prosthesis according to claim 5, characterized in that three or more  
2 mutually attached rings (7,8) placed on top of each other are used and that the stent (1) is  
3 made to be fixed through the expansion at one point in the channel where the valve  
4 prosthesis is inserted, which point is different from the point where the valve is  
5 mounted in the stent.

1 8. A valve prosthesis according to claim 1, characterized in that the cylinder  
2 surface of the support means is closed to form a tubular element (24)

1 9. A balloon catheter (11) for use in implantating a valve prosthesis (9)  
2 according to claim 1 and comprising a channel (15) for injection of a fluid for the  
3 inflation of the balloon means (13) of the catheter and an insertion cap (11A) wherein  
4 the balloon means (13) of the catheter and a collapsible valve prosthesis (9) mounted  
5 thereon are located during the injection, characterized in that the balloon means (13) are  
6 provided with profiled surface (14) which is made to ensure a steady fastening of the  
7 valve prosthesis (9) during the withdrawal of the balloon means (13) from the protection  
8 cap (11A) and the subsequent inflation for expanding the stent (1)

1 10. A balloon catheter according to claim 9, characterized in that the profiling of  
2 the surface is made by beads (14) or buds on the surface of the balloon means.

1 11. A balloon catheter according to claim 10, characterized in that the beads  
2 (14) are placed in pairs in a number from four to eight along lines parallel with the  
3 longitudinal axis (19) of the balloon means and with a spacing corresponding to the  
4 height of the stent (1) used .

1 12. A balloon catheter according to claim 9, characterized in that the profiling of  
2 the surface is made by an indentation which is formed in the surface of the balloon  
3 means (13) with an extension corresponding to the height of the stent (1) used.



## **A VALVE PROSTHESIS FOR IMPLANTATION IN THE BODY AND A CATHETER FOR IMPLANTING SUCH VALVE PROSTHESIS**

### **ABSTRACT OF THE DISCLOSURE**

- 5 A valve prosthesis (9) for implantation in the body by use of catheter (11) comprises a stent made from an expandable cylinder-shaped thread structure (2,3) comprising several spaced apices (4). The elastically collapsible valve (4) is mounted on the stent as the commissural points (5) of the valve (6) is secured to the projecting apices (4).
- 10 The valve prosthesis (9) can be compressed around the balloon means (13) of the balloon catheter (11) and be inserted in a channel, for instance in the aorta (10). When the valve prosthesis is placed correctly the balloon means (13) is inflated thereby expanding the stent and wedging it against the wall of the aorta. The balloon means is provided with beads (14) to ensure a steady fastening of the valve prosthesis on the
- 15 balloon means during insertion and expansion.

The valve prosthesis (9) and the balloon catheter (11) make it possible to insert a cardiac valve prosthesis without a surgical operation comprising opening the thoracic cavity.

- 20 (Figs. 2 and 3 are considered suitable to the published with the abstract).

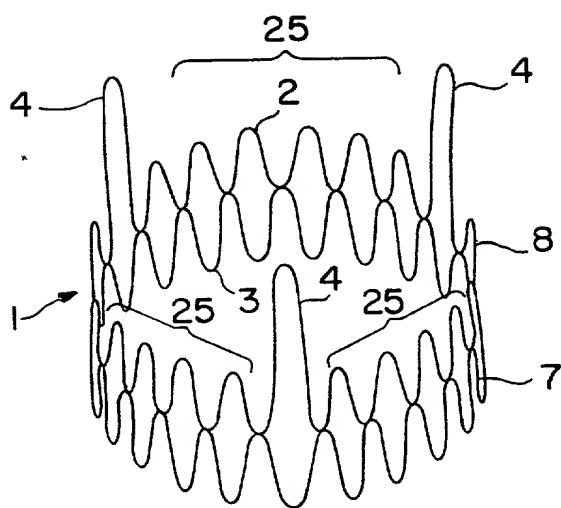


FIG. 1

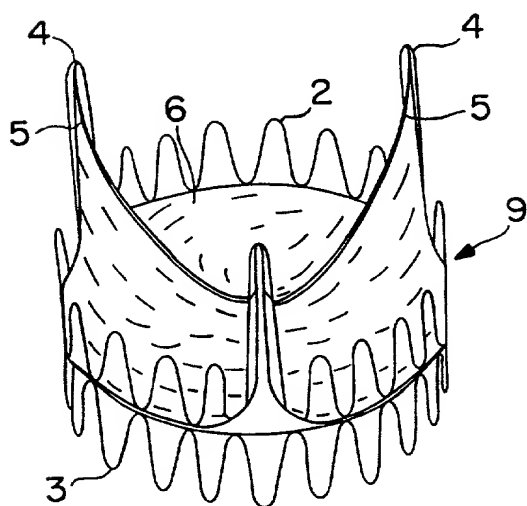
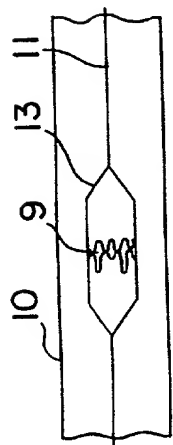
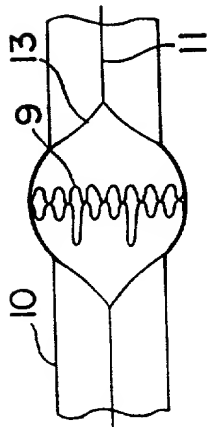


FIG. 2





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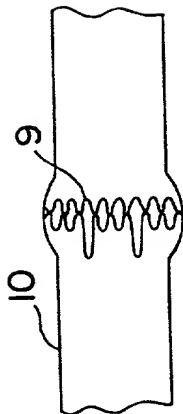
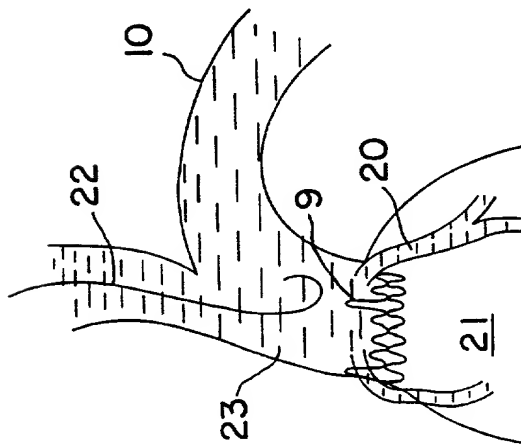
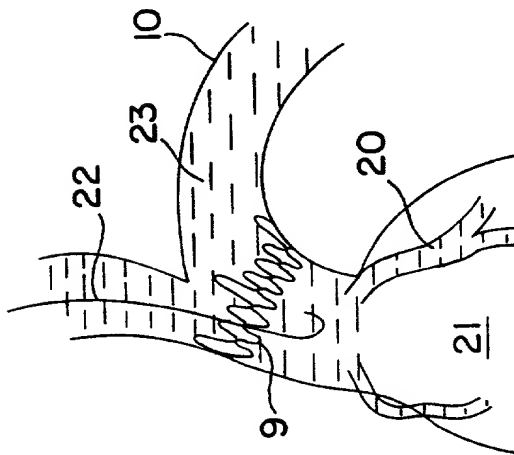


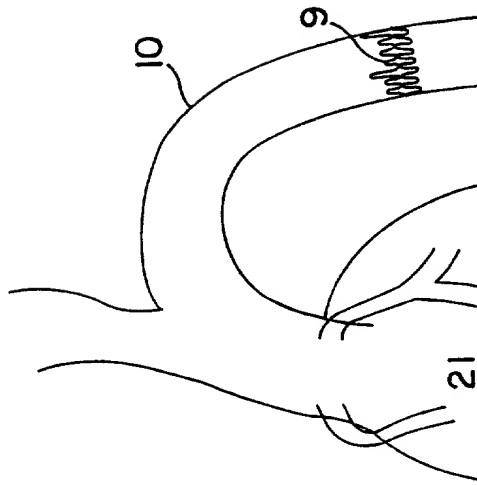
FIG. 7



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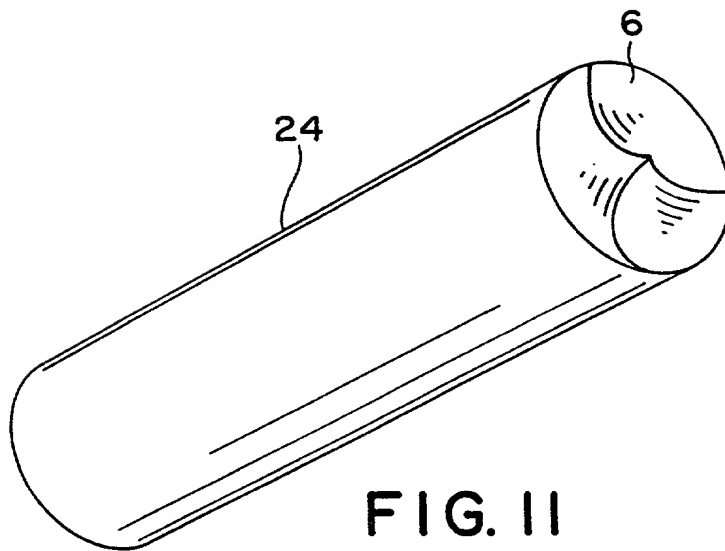
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FIG. 11

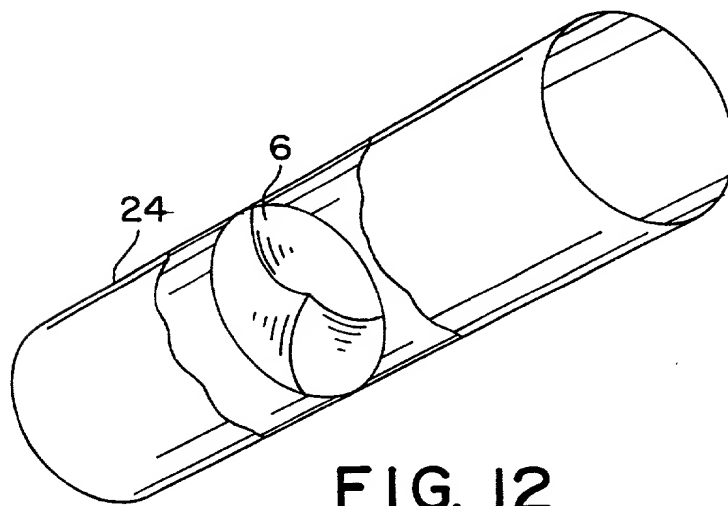


FIG. 12

## COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY

(Includes Reference to PCT International Applications)

ATTORNEY'S DOCKET NUMBER

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

A valve prosthesis for implantation in the body and a catheter for  
implantating such valve prosthesis

the specification of which (check only one item below):

☐ is attached hereto.

☐ was filed as United States application

Serial No. \_\_\_\_\_

on \_\_\_\_\_

and was amended

on \_\_\_\_\_ (if applicable).

☒ was filed as PCT international application

Number PCT/DK91/00134

on May 16, 1991

and was amended under PCT Article 19

on \_\_\_\_\_ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

## PRIOR FOREIGN/PCT APPLICATION(S) AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. 119:

COUNTRY (if PCT indicate PCT)	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 35 USC 119
Denmark	1246/90	18 May 1990	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO

**Combined Declaration For Patent Application and Power of Attorney (Continued)**  
 (Includes Reference to PCT International Applications)

ATTORNEY'S DOCKET NUMBER

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application:

**PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS DESIGNATING THE U.S. FOR BENEFIT UNDER 35 U.S.C. 120:**

U.S. APPLICATIONS		STATUS (Check one)		
U.S. APPLICATION NUMBER	U.S. FILING DATE	PATENTED	PENDING	ABANDONED

PCT APPLICATIONS DESIGNATING THE U.S.					
PCT APPLICATION NO.	PCT FILING DATE	U.S. SERIAL NUMBERS ASSIGNED (if any)			

**POWER OF ATTORNEY:** As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. (List name and registration number)

Send Correspondence to:

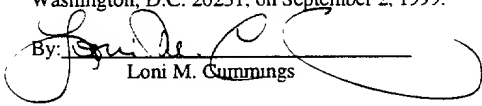
 Direct Telephone Calls to:  
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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

SIGNATURE OF INVENTOR 201 <i>Henning Rud Andersen</i>	SIGNATURE OF INVENTOR 202 <i>John Michael Hasenkam</i>	SIGNATURE OF INVENTOR 203 <i>Lars Lyhne Knudsen</i>
DATE 17 December 1992	DATE 17. December 1992	DATE 17. December 1992

I hereby certify that this correspondence is being deposited  
with the United States Postal Service as first class mail in  
an envelope addressed to: Assistant Commissioner for Patents,  
Washington, D.C. 20231, on September 2, 1999.

By:   
Loni M. Cummings

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of )

HENNING R. ANDERSEN, *et al.* )

Examiner: J. Smith

Application No.: 09/026,574 )

Art Unit: 3732

Filed: February 20, 1998 )

For: VALVE PROSTHESIS FOR )  
IMPLANTATION IN THE BODY )  
AND A CATHETER FOR )  
IMPLANTING SUCH VALVE )  
PROSTHESIS )

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